510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
k041728

B. Purpose for Submission:
New device

C. Analyte:
Human Chorionic Gonadotropin (hCG)

D. Type of Test:
Qualitative

E. Applicant:
Immunostics, Inc.

F. Proprietary and Established Names:
hCG Detector Combi ™
hCG Detector™ -Urine
hCG Detector Stix™

G. Regulatory Information:

1. Regulation section:
   21 CFR 862.1155 Human Chorionic Gonadotropin (hCG) test system
2. Classification:
   Class II
3. Product Code:
   JHI
4. Panel:
   75

H. Intended Use:

1. Intended use(s):
   The Immuno/hCG Detector Combi™ is for the rapid and qualitative determination of Human Chorionic Gonadotropin (hCG) in urine or serum. It is intended for professional and laboratory use only.
   The immuno/hCG Detector™-Urine is for the rapid and qualitative determination of Human Chorionic gonadotropin (hCG) in urine. It is intended for professional and laboratory use only.
   The Immuno/hCG Detector Stix™ is for the rapid and qualitative determination of Human Chorionic gonadotropin (hCG) in urine. It is intended for professional and laboratory use only.
2. Indication(s) for use:
   See above..
3. Special condition for use statement(s):
   This device is intended for clinical laboratory and physician's office laboratory (POL) use.
4. Special instrument Requirements:
   Not applicable

I. Device Description:

The immuno/hCG Detector has three separate formants: hCG Detector Combi™(25 tests per box), hCG Detector™-Urine(25 tests per box) and hCG Detector Stix™ (50 tests per box). The hCG Detector Combi™ and the hCG Detector™- Urine both consists of one hCG Detector Cassette, a disposable specimen dropper in a foil pouch and instructions. The hCG Detector Stix™ test consists of one Immuno hCG Detector strip.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   UniMark hCG Combo
   UniStep hCG Pregnancy Test
   ACON One Step Pregnancy Strip
2. Predicate K number(s):
   Unimark hCG Combo K01394
   UniStep hCG Pregnancy Test K941090
   ACON One Step Pregnancy Strip K993203
3. Comparison with predicate:

Immuno/hCG Detector Combi™

Similarities		
Item	**Device**	**Predicate**
Intended Use	The Immuno/hCG Detector Combi™ is for the rapid and qualitative determination of Human Chorionic Gonadotropin (hCG) in urine or serum. It is intended for professional and laboratory use only.	The UniMark® hCG Combo Pregnancy Test Device is for the rapid and qualitative determination of Human Chorionic Gonadotropin (hCG) in urine or serum. It is intended for professional and laboratory use only.
Matrix	Urine or Serum	Urine or Serum
Sample Size	150 uL	150 uL
Principle/Methodology	Lateral Flow Chromatographic Immunoassay	Lateral Flow Chromatographic Immunoassay
	Mouse monoclonal and Goat polyclonal antibodies	Mouse monoclonal and Goat polyclonal antibodies
Item	**Device**	**Predicate**
Detection Level	20 mIU/mL	25 mIU/mL
Test Time	5 minutes for Urine 5 minutes for Serum	5 minutes for Urine 7 minutes of Serum

Immuno/ hCG Detector™-Urine

Similarities		
Item	**Device**	**Predicate**
Intended Use	The Immuno/hCG Detector ™-Urine is for the rapid and qualitative determination of Human Chorionic Gonadotropin (hCG) in urine. It is intended for professional and laboratory use only.	The UniMark® hCG Pregnancy Test Device is for the rapid and qualitative determination of Human Chorionic Gonadotropin (hCG) in urine. It is intended for professional and laboratory use only.
Matrix	Urine	Urine
Sample Size	150 uL	150 uL
Principle/Methodology	Lateral Flow Chromatographic Immunoassay	Lateral Flow Chromatographic Immunoassay
	Mouse monoclonal and Goat polyclonal antibodies	Mouse monoclonal and Goat polyclonal antibodies
Item	**Device**	**Predicate**
Detection Level	20 mIU/mL	25 mIU/mL
Test Time	5 minutes for Urine	5 minutes for Urine

Immuno/ hCG Detector Stix™

Similarities		
Item	**Device**	**Predicate**
Intended Use	The Immuno/hCG Detector Stix ™ is for the rapid and qualitative determination of Human Chorionic Gonadotropin (hCG) in urine. It is intended for professional and laboratory use only.	The UniMark® hCG Pregnancy Test Device is for the rapid and qualitative determination of Human Chorionic Gonadotropin (hCG) in urine. It is intended for professional and laboratory use only.
Matrix	Urine	Urine
Sample Size	150 uL	150 uL
Principle/Methodology	Lateral Flow Chromatographic Immunoassay	Lateral Flow Chromatographic Immunoassay
	Mouse monoclonal and Goat polyclonal antibodies	Mouse monoclonal and Goat polyclonal antibodies
Item	**Device**	**Predicate**
Detection Level	20 mIU/mL	25 mIU/mL
Test Time	5 minutes for Urine	5 minutes for Urine

K. Standard/Guidance Document Referenced (if applicable):

1) Review Criteria for Assessment of Professional Use Human Chorionic Gonadotropin (hCG) In Vitro Diagnostic Devices, CDRH Guidance Document Nov.6, 1996
2) ISO13485:996 First Edition 1996-12-15 Quality Systems-Medical Devices with Particular Requirements for Application of ISO 9001, Second Addition 1994-07-01, the International Organization for Standards.

L. Test Principle:

This device is a solid phase, sandwiched chromatographic immunoassay.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:
See Below

b. Linearity/assay reportable range:
Not Applicable

c. Traceability (controls, calibrators, or method):
All three detectors were calibrated with WHO 3rd I.S.

d. Detection limit:
The sensitivity of all three devices is 20 mIU/mL in serum or urine.

Immuno/ hCG Detector Combi™
20 urine and 20 serum clinical samples obtained from normal (non-pregnant) individuals were spiked with hCG to the concentrations of 5, 15, 20, 25, 50 mIU/mL and were tested. hCG levels in serum and urine that were greater than or equal to 15 mIU/mL was positive 100% of the time. hCG levels in serum and urine of 0 and 5 mIU/mL were negative 100% of the time.

Immuno/ hCG Detector ™ -Urine
20 urine clinical samples obtained from normal (non-pregnant) individuals were spiked with hCG to the concentrations of 5, 15, 20, 25, 50 mIU/mL and were tested. hCG levels urine that were greater than or equal to 15 mIU/mL was positive 100% of the time. hCG levels in urine of 0 and 5 mIU/mL were negative 100% of the time.

Immuno/ hCG Detector Stix™-Urine
20 urine clinical samples obtained from normal (non-pregnant) individuals were spiked with hCG to the concentrations of 5, 15, 20, 25, 50 mIU/mL and were tested. hCG levels urine that were greater than or equal to 15 mIU/mL was positive 100% of the time. hCG levels in urine of 0 and 5 mIU/mL were negative 100% of the time.

e. Analytical specificity:
All three devices were tested and were found non-reactive in specimens spiked with Luteinizing Hormone (hLH at 300mIU/mL), Follicle Simulating Hormone (hFSH at 1000 mIU/mL) and Thyroid Stimulating Hormone (hTSH at 1000 uIU/mL).

Commonly found substances (Prescription, OTC, chemical and biological analytes) were spiked into specimens containing 0, 20 and 100 mIU/mL hCG and did not effect the test results.

f. Assay cut-off:
20 mIU/mL for all three devices

2. Comparison studies:

a. Method comparison with predicate device:
All three devices were tested and compared to the Biotech Atlantics UniMark Device predicate at three POLs (physicians office laboratories). See the chart below. The device was compared to the predicate and the results are shown in the chart below. The urine samples were selected and supplied by the POLs through routine pre-screened test material from women of childbearing age. The serum samples were supplied as coded samples consisting of 20 negatives and 20 positives, with 8/20 positives within + 20% of the cutoff value of 20 mIU/mL.

Device	# of Samples Tested	Matrix	# of positive results	# of Negative results	% Agreement to predicate
Immuno/ hCG Detector Combi™	141	Urine	65	76	100
Immuno/ hCG Detector Combi™	120	Serum	59	61	100
Immuno/ hCG Detector ™ -Urine	133	Urine	62	71	100
Immuno/ hCG Detector Stix™-Urine	133	Urine	61	72	100

b. Matrix comparison:
Not applicable

3. Clinical studies:

a. Clinical sensitivity:
Not applicable

b. Clinical specificity:
Not applicable

c. Other clinical supportive data (when a and b are not applicable):
Not applicable

4. Clinical cut-off:
See detection limit above.

5. Expected values/Reference range:
Expected values were established in the literature.

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.